14. Suitability for PrEP - Parallel of Chapter 4

The guidance on PrEP suitability in this chapter is identical to the guidance provided in Chapter 4 on PrEP suitability. However this chapter is written for clinicians who prefer to and are skilled in evaluating people's suitability for PrEP according to how the person reports their gender identity and sexuality. For example a person assigned female at birth (cis-female) may identify their gender as male (trans-male) and their sexuality as a man who has sex with men (MSM). In this setting, the clinician would know to evaluate the person's suitability for PrEP based on the possibility that the person may practice both vaginal and anal sex. Alternatively a person assigned male at birth (cis-male) may identify their gender as female (trans-female) and their sexuality as heterosexual. If this person has undertaken gender-affirming surgery the clinician would then know to evaluate the person's suitability for PrEP based on the possibility that the person may practice both vaginal and anal sex. This Parallel of Chapter 4 foreshadows a future where all clinicians will be able to skilfully and comfortably evaluate the sexual health of their patients based on how their patients identify their gender and sexuality. For more information see: a language guide: Trans and gender diverse inclusion.

Pre-exposure prophylaxis (PrEP) medications are registered in Australia with the Therapeutic Goods Administration (TGA) and they are subsidised by the Australian Pharmaceutical Benefits Scheme (PBS). All general practitioners and other medical specialists can prescribe PrEP using a PBS streamlined authority arrangement. No specialist training is required to prescribe PrEP, however resources and training guidance are available for clinicians who are new to prescribing PrEP.

People presenting for PrEP are typically at high risk of human immunodeficiency virus (HIV) infection and they should not be dissuaded from using PrEP. To do so is to deny a person access to one of the most effective HIV prevention tools currently available. Doctors authorised nurse practitioners who are not comfortable prescribing PrEP should refer the patient immediately to a colleague, or another service that does provide PrEP.

It should also be highlighted that sexual history taking is a necessary and routine part of medical practice, and when this process identifies that a patient may be at risk of HIV, clinicians should proactively offer

these patients PrEP. Furthermore clinicians are encouraged to raise PrEP as an HIV prevention strategy with patients whom they perceive to be at risk of HIV infection, even if the purpose of the patient's visit is not related to sexual health, sexually transmissible infections (STIs) or drug use.

These ASHM 2019 PrEP guidelines recommend daily PrEP for all people at risk of HIV infection. In addition, these guidelines also recommend that on-demand PrEP should be offered as an alternative option to cis-gender men who have sex with men (MSM). Please refer to section Providing PrEP for further information on initiating PrEP.

PrEP providers need to obtain a thorough sexual and drug-use history at baseline to determine a person's suitability for PrEP and to review their ongoing need for PrEP at each 3-monthly clinical review. It is important to acknowledge that a person's behaviour may change over time, and that a person may wish to continue PrEP even if their current HIV acquisition risk is not high.

These guidelines acknowledge that PrEP should be recommended as an HIV prevention strategy for people who have been at risk of HIV infection during the previous 3 months and who foresee having similar risks in the next 3 months. These guidelines also recommend PrEP for people who have not been at risk of HIV infection during the previous 3 months, but whose circumstances have changed, and they foresee HIV risk occurring in the next 3 months.

Please note that people who are eligible for PrEP based on their sexual behaviour may be simultaneously eligible for PrEP based on their injecting and other drug use behaviour and vice versa.

The following suitability criteria can be used to help structure a discussion with a patient about their sexual health and behaviour. Guidance on how to initiate and guide a discussion about a person's sexual and drug using behaviour in primary practice is available (1).

Only a small proportion of participants in PrEP studies have been transgender (trans) or gender diverse people (2, 3, 4). As a result, limited data are available for these populations. Incorrect assumptions can be made about trans people and their sexual practices, as they may practice vaginal/neovaginal and anal intercourse, both insertive and receptive. Trans and gender-diverse people who are at risk of acquiring HIV on the basis of their sexual history are eligible to access PrEP. It is essential for clinicians to take a sexual history using appropriate and sensitive language to assess risk.

Clinicians who have limited experience with prescribing PrEP are encouraged to discuss with a PrEP experienced clinician those patients whose PrEP suitability is unclear.

PrEP suitability criteria for men who have sex with men

This section addresses PrEP suitability for MSM. This section is relevant to people who were assigned male at birth and identify as male, known as cis-men. This section is also relevant to people who were assigned female at birth but identify as male, known as trans-men. Of note, trans-men who have sex with men may practice both anal and vaginal sex.

Box 14.1 PrEP suitability criteria for men who have sex with men

HIV risk in the previous 3 months and the future 3 months

The clinician should prescribe PrEP if the patient describes a history of any of the following HIV acquisition risks in the previous 3 months and if the patient foresees that there are likely to be similar acquisition risks in the next 3 months:

- At least one episode of condomless anal intercourse (insertive or receptive) with a regular HIV-positive partner who is either not on treatment, or who is on treatment but has a detectable HIV viral load
- At least one episode of receptive condomless anal intercourse with any casual male partner
- At least one episode of condomless receptive vaginal sex with a regular HIV+ partner who is either not on treatment, or who is on treatment but has a detectable HIV viral load
- At least one episode of receptive condomless vaginal sex with any casual HIV+ male partner, or a male partner whose HIV status is unknown
- More than one episode of vaginal sex where a condom slipped off or broke where the HIV serostatus of the partner was not known, or where the partner was HIV+ and not on treatment or had a detectable viral load on treatment
- One or more episodes of engaging in sexualised drug use, sometimes referred to as 'chemsex'. In the Australian context this typically involves the use of crystal methamphetamine (Ice), but can also include the use of gamma hydroxybutyrate (GHB)
- One or more episodes of rectal/vaginal gonorrhoea, rectal/vaginal chlamydia, or infectious syphilis, including any STIs diagnosed at screening for PrEP
- More than one episode of anal intercourse where a condom slipped off or broke where the HIV serostatus of the partner was not known, or where the partner was HIV positive and not on treatment or had a detectable viral load on treatment.

HIV risk in the future 3 months

The clinician should prescribe PrEP if the patient foresees that they will have HIV acquisition risk in the upcoming 3 months, despite not having had HIV acquisition risk in the previous 3 months.

Note: The following list is not exhaustive and there are likely to be many other scenarios where PrEP could be suitably offered for people whose HIV risk acquisition is exclusively in the future:

- When a person plans to travel during which time they anticipate that they will be having condomless sex with casual partners
- When a person plans to return home to an overseas country which has a high HIV prevalence during which time they anticipate that they will be having condomless sex with casual partners
- When a person reports that they have recently left a monogamous relationship and will be having condomless sex with casual partners in the future
- When a person reports that they will be entering or leaving institutional or correctional facilities in the near future where they may have condomless sex with casual partners in the future
- When a person presents with concerns of deteriorating mental health and a history of having previously increased their HIV acquisition risk behaviour in this setting
- When a person presents with a history of intermittent binge drinking of alcohol or recreational drug use and a history of having had increased their HIV acquisition risk behaviour in this setting.

The clinician should consider prescribing PrEP also in the following circumstances:

- When an HIV serodiscordant couple experience undue suffering and anxiety about inter-couple HIV transmission despite the positive partner being virologically suppressed on treatment
- When a person reports being so anxious about HIV infection that it may prevent them from having regular HIV testing, or engaging in any form of anal sex
- When a person presents with a history of recurrent genital ulceration or dermatoses (e.g. psoriasis), as this may increase the risk of HIV transmission.

PrEP suitability criteria for heterosexuals

This section addresses PrEP suitability for heterosexuals. This section is relevant to the following populations: (i) people who were assigned female at birth (cis-female), identify as female and as heterosexual; (ii) people who were assigned male at birth (cis-male), identify as male and identify as heterosexual; (iii) people who were assigned male at birth (cis-male), identify as female (trans-female) and identify as heterosexual and (iv) people who were assigned female at birth (cis-female), identify as male (trans-male) and identify as heterosexual.

Box 14.2 PrEP suitability criteria for heterosexuals

HIV risk in the previous 3 months and the future 3 months

The clinician should prescribe PrEP if the patient describes a history of any of the following HIV acquisition risks in the previous 3 months and if the patient foresees that there are likely to be similar acquisition risks in the next 3 months.

- At least one episode of condomless anal or vaginal intercourse (insertive or receptive) with a regular HIV-positive partner who is either not on treatment, or who is on treatment but has a detectable HIV viral load
- At least one episode of receptive anal or vaginal condomless intercourse with any casual HIV-positive partner or a male bisexual partner of unknown status
- Episodes of planned condomless insertive or receptive vaginal sex in an effort to conceive with an HIV-positive partner, regardless of the HIV-positive partner's viral load.

HIV risk in the future 3 months

The clinician should prescribe PrEP if the patient foresees that they will have HIV acquisition risk in the upcoming 3 months, despite not having had HIV acquisition risk in the previous 3 months:

- Future episodes of planned condomless insertive or receptive vaginal sex in an effort to conceive with an HIV-positive partner, regardless of the HIV-positive partner's viral load
- When a person plans to travel to countries with high HIV prevalence during which time they anticipate having condomless sex with casual partners who are HIV positive or of unknown HIV serostatus
- When a person plans to return home to an overseas country which has a high HIV prevalence during which time they anticipate that they will be having condomless sex with casual partners
- When a person reports that they have recently left a monogamous relationship and will be having condomless sex with a casual HIV-positive partner, or a male or female partner of unknown HIV serostatus from a country with high HIV prevalence, or a male partner who is thought to have sex with men
- When an individual reports that they will be entering, or leaving institutional or correctional facilities in the near future where they may have condomless sex with HIV+ or gay or bisexual male casual partners in the future
- When a person presents with concerns of deteriorating mental health and a history of having had increased their HIV acquisition risk behaviour in this setting
- When a person presents with a history of intermittent binge drinking of alcohol or recreational drug use and a history of having had increased their HIV acquisition risk behaviour in this setting.

The clinician should consider prescribing PrEP also in the following circumstances:

- When an HIV serodiscordant couple experience undue suffering and anxiety about inter-couple HIV transmission despite the positive partner being virologically suppressed on treatment.

PrEP suitability criteria for people who inject drugs

In the first instance, people who inject drugs (PWID) should be advised of and provided with options for using sterile needles, syringes and other injecting equipment, and offered opioid substitution therapy for those who use opioids. People who inject drugs can be referred to local needle and syringe programs, or the Australian Injecting and Illicit Drug Users League affiliates in their state or territory.

Because PWID are susceptible to a range of infections and injuries, PrEP and other HIV-prevention interventions should be integrated into prevention and clinical care services for hepatitis A, B and C infection and other infectious diseases, and overdose prevention. These interventions include screening for hepatitis A, B and C viruses and providing incentivised vaccination for hepatitis A and B where clinically indicated, as well as screening for injection-related injuries and infections including abscesses, septicaemia and endocarditis (5).

The ASHM PrEP Guidelines Panel is cognisant of the concerns of the International Network of People who Use Drugs. The Network cautions against prioritising PrEP at the expense of other proven interventions as the prime HIV-prevention strategy for people who inject drugs, and emphasises that access to harm-reduction services remains a critical component of HIV prevention in people who inject drugs (6). This approach is particularly relevant in Australia where sterile needle and syringe coverage is high and HIV prevalence and incidence among people who inject drugs remains low and stable (7, 8).
A recent systematic review of HIV-treatment adherence among PWID in the United States and Canada, undertaken to inform potential PrEP adherence interventions for people who inject drugs, found that younger age, female sex, homelessness and incarceration were obstacles to HIV treatment adherence (9). By comparison, self-sufficiency, use of opioid substitution therapy, and high quality patient-provider relationships were facilitators for adherence (9). Self-reports from HIV-negative people who inject drugs were that HIV–related stigma in social networks, negative experiences with health-care providers, lack of money, homelessness and the criminal justice system were likely barriers to PrEP access (10). These factors should be considered when providing support to people commencing PrEP when they are at risk of HIV through injecting drug use.

The ASHM PrEP Guidelines Panel will continue to monitor the outcomes of the few ongoing studies of HIV PrEP in PWID.

Box 14.3 PrEP suitability criteria for people who inject drugs

HIV risk in the previous 3 months and the future 3 months

The clinician should prescribe PrEP if the patient describes a history of any of the following HIV acquisition risks in the previous 3 months and if the patient foresees that there are likely to be similar acquisition risks in the next 3 months:

- Shared injecting equipment with an HIV-positive person or with a gay or bisexual man of unknown HIV status
- At least one episode of condomless anal or vaginal intercourse (insertive or receptive) with a regular HIV-positive partner who is either not on treatment, or who is on treatment but has a detectable HIV viral load
- At least one episode of receptive anal or vaginal condomless intercourse with any casual HIV-positive partner or a male homosexual or bisexual partner of unknown status.

HIV risk in the future 3 months

The clinician should prescribe PrEP if the patient foresees that they will have HIV acquisition risk in the upcoming 3 months, despite not having had HIV acquisition risk in the previous 3 months.

- A person has recently (re)commenced injecting drugs and is injecting with a person who is HIV positive, or with a gay or bisexual man whose HIV status is unknown
- When a person plans to travel to countries with high HIV prevalence during which time they anticipate injecting drugs with other people who are HIV positive or of unknown HIV serostatus
- When a person reports that they will be entering, or leaving institutional or correctional facilities in the near future during which time they may inject drugs with people who are HIV positive or of unknown HIV serostatus

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